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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,115	04/04/2001	Gwong-Jen J. Chang	14114.0332U3	4134
46135	7590	11/29/2005	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE 1600 PORTLAND, OR 97204			PARKIN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/826,115	<b>Applicant(s)</b> CHANG, GWONG-JEN J.	
	<b>Examiner</b> Jeffrey S. Parkin, Ph.D.	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-17,28,32,34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-15,17,28,32,34 and 36 is/are allowed.
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/17/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

Serial No.: 09/826,115  
Applicant: Chang, G.-J.

Docket No.: 14114.0332U3  
Filing Date: 04/04/01

## Detailed Office Action

### *Status of the Claims*

Acknowledgement is hereby made of receipt and entry of the communication received 17 August, 2005. Claims 1, 3-17, 28, 32, 34, and 36 are pending in the instant application.

### *35 U.S.C. § 112, Second Paragraph*

The previous rejection of claims 1, 3-17, 28, 32, 34, and 36 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to applicant's amendment.

### *35 U.S.C. § 103(a)*

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The previous rejection of claims 1, 3-17, 28, 32, 34, and 36 under 35 U.S.C. § 103(a) as being unpatentable over Yasui et al. (1990) in view of Kochel et al. (2002) and Ivy et al. (2000), is hereby withdrawn in response to applicant's amendment and arguments.

**35 U.S.C. § 101**

The following is a quotation of the first paragraph of 35 U.S.C. § 101 which reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 16 is rejected under 35 U.S.C. § 101, because the claimed invention is directed to non-statutory subject matter. The term "cell" as defined by the specification (e.g., see p. 20) states that the cell is present in a human being and is therefore inseparable from the human itself.<sup>1</sup> The scope of the claim, therefore, encompasses a human being which is non-statutory subject matter. Amendment of the claim language to recite

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<sup>1</sup> The disclosure states on page 20 (lines 1-14) that "As used herein, a "cell" is a prokaryotic or eukaryotic cell comprising a TU coding for one or more gene products, or into which such a TU has been introduced. Thus, a cell harbors a foreign or heterologous substance, the TU, which is not naturally or endogenously found in the cell as a component. A suitable cell is one which has the capability for the biosynthesis of the gene products as a consequence of the introduction of the TU. In particular, a suitable cell is one which responds to a control sequence and to a terminator sequence, if any, that may be included within the TU. In important embodiments of the present invention, the cell is a mammalian cell. **In particularly important embodiments of this invention, the cell is a naturally occurring cell in the body of a human or nonhuman subject to whom (which) the TU has been administered as a component of a vaccine. Alternatively, in analytical, or diagnostic applications, including preparation of antigen for use as a vaccine or in immunodiagnostic assays, or for demonstrative purposes, the cell may be a human or nonhuman cell cultured in vitro.**"

"isolated", "purified", or "non-human" would be remedial. See 1077 O.G. 24, April 21, 1987.

#### **Allowable Subject Matter**

Claims 1, 3-15, 17, 28, 32, 34, and 36 are free of the prior art of record and are allowable.

#### **Correspondence**

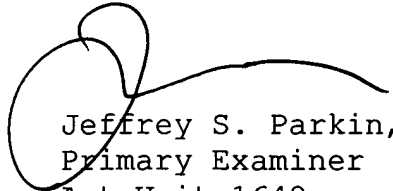
Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

A handwritten signature in black ink, appearing to read "Jeffrey S. Parkin", is written over the typed name and title.

Jeffrey S. Parkin, Ph.D.  
Primary Examiner  
Art Unit 1648

25 November, 2005